2000 WL 805221
Fed. Sec. L. Rep. P 91,001
(Cite as: 2000 WL 805221 (E.D.Pa.))

United States District Court, E.D. Pennsylvania.

In re CELL PATHWAYS, INC., Securities Litigation.

No. 99-725.

June 20, 2000.

MEMORANDUM

KELLY.

***1** This securities fraud class action is a consolidation of five related cases brought pursuant to Federal Rules of Civil Procedure 23(a) and 23(b), on behalf of a class of persons who purchased common stock at allegedly artificially inflated prices from Cell Pathways, Inc. ("CPI") during the period from October 7, 1998 to February 2, 1999 (the "Class Period.") In their Consolidated Amended Complaint, filed on June 28, 1999, Plaintiffs allege that CPI [FN1] made false and misleading statements regarding the testing and status of the development of one of its products, a drug named exisulind, in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. § § 78j(b) and 78t(a), and Rule 10 b 5 promulgated thereunder, 17 C.F.R. § 240.10b 5. On September 21, 1999, CPI filed a Motion to Dismiss, which this Court denied by Order dated January 27, 2000. On February 10, 2000, CPI filed a Motion for Reconsideration of the January 27, 2000 Order, along with an Application for Order Certifying Immediate Appeal under 28 U.S.C. § 1292(b), both of which were denied by Order dated March 16, 2000. CPI then filed the instant Petition for Writ of Mandamus in the United States Court of Appeals for the Third Circuit (the "Third Circuit"). The following discussion details the basis for this Court's refusal to dismiss the Complaint.

FN1. This case also includes two individual defendants, Robert Towarnicki, Chief Executive Officer of CPI, and Rifat Pamucku, Chief Scientific Officer of CPI. For purposes of this Memorandum, we will refer to the defendants collectively as CPI except at such times as their individual identities are relevant to the issues discussed herein.

I. BACKGROUND.

The relevant facts of this case, as pleaded in the Complaint and taken as true for purposes of this Motion, are as follows. CPI is a bio pharmaceutical company located in Horsham, Pennsylvania, which is engaged in the business of developing products to prevent and treat cancer. CPI began trading on the NASDAQ National Market on November 4, 1998 and continued to trade its common stock throughout the Class Period.

Plaintiffs assert that since the 1980's, scientists have known that certain non-steroidal anti-inflammatory drugs ("NSAIDs") could cause precancerous colon polyps to regress and could also prevent their recurrence. However, because these drugs result in significant gastrointestinal irritation and kidney toxicity, their long term usefulness is limited.

In 1991, CPI discovered a new compound that it believed would be useful in the treatment of colonic polyps and the prevention of colon cancer. This compound, called exisulind, is believed to inhibit the growth of and to trigger apoptosis, or "programmed cell death," in certain premalignant and malignant cells without the adverse side effects of NSAIDs. The first clinical trials for exisulind began as a treatment for precancerous and cancerous lesions in patients with adenomatous polyposis coli ("APC"). APC is a rare condition in which patients form intestinal polyps which progress to colon cancer if untreated. Presently, exisulind is CPI's leading product candidate, and CPI has done more clinical testing of exisulind for APC than for any other indication.

CPI obtained a "Fast Track" designation from the FDA for exisulind for the treatment of APC. Under the Fast Track Program, the FDA can expedite consideration of drugs that evidence the potential to address medical needs in treating serious or life threatening illnesses. Before a biological product can be marketed in the United States it must undergo an approval process by the FDA, completion of preclinical studies, and a New Drug Application ("NDA") must be filed with the FDA. Preclinical studies are performed on animals and the results are submitted to the FDA as part of the NDA. Human clinical studies may not be commenced until the NDA application has become effective pursuant to FDA regulations.

***2** The clinical investigation of a new biological product usually occurs in sequential phases pursuant

to a written protocol, which is submitted to the FDA as part of the NDA. Phase I, the first clinical evaluation, consists of testing the product for safety, tolerable dosage, etc., on a small number of humans. Phase II involves larger trials at different dosage levels to evaluate the safety and tolerable dosage levels of the product and to assess the effectiveness of the product in humans affected with the disease. Phase III studies consist of additional testing to establish safety and effectiveness in a larger group of patients at different test sites. Once Phase III has been completed, the results of the clinical trials are submitted to the FDA in the form of a Product License Application for approval of commercial sales, which is followed by an NDA.

CPI commenced its Phase I studies for exisulind in 1994. In August, 1995, CPI began a six-month Phase I/II dose-ranging safety study of the drug for APC involving 18 patients. Plaintiffs assert that prior to the Class Period, CPI repeatedly stated that it expected to conclude all Phase III trials for APC and file an NDA by January, 1999.

During the first two trials, Plaintiffs assert that CPI issued statements concerning exisulind's apparent success in treating APC. On May 20, 1998, CPI allegedly announced that the APC study results demonstrated exisulind's ability to prevent precancerous polyps, and that 18 patients taking the drug for 18 months following the completion of the Phase I/II trial appeared to be reacting positively.

On July 9, 1998, Plaintiffs contend that CPI announced that it had received "Fast Track" designation by the FDA, and stated that this designation underscored "the potential of exisulind to address important unmet needs for [APC] patients." Moreover, based upon the results of the APC trials, CPI initiated studies of exisulind as a treatment for other types of cancers. In March of 1998, at an American Association of Cancer Research meeting, a Company researcher allegedly stated that CPI's lead compound might have potential in fighting lung cancer.

On October 7, 1998, Plaintiffs contend that CPI announced that it had filled its enrollment in the Phase III study of exisulind in the treatment of prostate cancer. CPI issued a press release in which it stated that it would complete its "pivotal" Phase III study for APC in January, 1999. Plaintiffs contend that this statement, which was exciting news for people, was misleading because CPI did not disclose a "fundamental flaw" in the process for selecting enrollees which created a grave risk that the Phase III trial would have unacceptable results and would be unacceptable to the FDA. Specifically, Plaintiffs claim that it was later learned that the physicians who referred the patients for the study were inadequately informed about APC and therefore only a sampling of the members of the study were within the target group. Plaintiffs also allege that the medical records of these patients were not studied closely enough to prevent this error.

***3** Notwithstanding these alleged flaws in the trial, in November, 1998 CPI allegedly released a press release in which Defendant Towarnicki commented that CPI had obtained "the funds necessary to implement the planned commercialization" of exisulind in 1999." Defendant Towarnicki allegedly also stated that CPI was "moving aggressively forward" with clinical development of exisulind. He further stated that exisulind was completing a pivotal Phase III trial for the treatment of APC, and that CPI expected to complete the trial in January of 1999 and to file a NDA in the first half of 1999. Plaintiffs argue that CPI's knowledge that the enrollees in the Phase III trial had been selected in a flawed manner rendered the above press release misleading, in that CPI failed to disclose the problems with the trial.

From November 7, 1998 to November 11, 1998, CPI's stock prices dropped. Plaintiffs argue that in response to this drop, CPI attempted to bolster market confidence by issuing a press release on November 18, 1998 in which it stated that it knew of "no material developments regarding CPI's research and development programs which would account for the recent trading patterns in CPI's common stock." In addition, the press release further stated that all of CPI's development efforts were proceeding as planned. Plaintiffs contend that it was materially misleading for CPI to deny that it knew of any problems regarding CPI's development programs when it knew its method of enrollment was flawed.

On December 11, 1998, CPI issued another press release in which it stated that its "experimental [exisulind] drug shows promise for cancer therapy" and that it expected a U.S.Patent to be awarded soon. It further stated that CPI planned to file with the FDA for marketing approval by the end of March, 1999. The price of CPI's stock allegedly increased in reaction to this announcement.

CPI completed its Phase III study in January of 1999, with 65 of the 73 patients completing the one year course of treatment. On February 1, 1999, CPI

announced in a press release that preliminary analysis suggested that the study did not receive a statistically significant clinical response with regard to the exisulind patients as compared to placebo patients during the Phase III trial, and that it would require weeks to evaluate the data. CPI also announced that there might be a delay in its filing the NDA with the FDA for exisulind for APC. CPI's stock price dropped significantly in reaction to this news.

In an interview with the *Bloomberg Forum* on February 2, 1999, Defendant Towarnicki explained that the results of the Phase III trial may have been due to design flaws in patient selection, and indicated his intention to review the findings of the trial.

The parties' interpretations of CPI's next press release, occurring on June 15, 1999, significantly diverge. On that date, CPI announced that 34 of the 65 patients who participated in the Phase III trial for exisulind fell within the target population for the study, i.e., those forming between ten and forty polyps per year. Plaintiffs interpret this statement to mean that the Phase III study was unsuccessful, as "the inclusion of so many ineligible participants had drastically reduced the size of the study's usable sample, thereby causing the overall results to be insufficient to satisfy FDA requirements." Plaintiffs also contend that at this time CPI indicated that although it planned to go forward with its plan to file an NDA with the FDA, the FDA would require the NDA to be "supplemented by information concerning the test results from additional persons who actually did fall within the target population."

***4** CPI contends, on the other hand, that the June 15, 1999 statement demonstrated that the trial was in facta success since "the Phase III study data revealed a higher degree of variability in polyp formation by APC patients that previously thought by experts in the disease," regardless of the fact that only 34 out of 65 patients fell within the targeted patient group.

The crux of Plaintiffs' claim is that the positive statements of CPI described above were misleading in that CPI continued to publish positive information concerning the status and development of exisulind while CPI knew of the flaws in the Phase III study. Plaintiffs contend that certain of CPI's comments reveal that it possessed enough information to support Plaintiffs' allegations of recklessness. Plaintiffs assert that CPI attributed the enrollment error to a general lack of understanding of APC, a rare disease, in the scientific community, and that such knowledge would indicate especially pervasive risks in designing, planning and carrying out a Phase III clinical trial. Plaintiffs also contend that CPI's public comments provide a strong inference that CPI at least recklessly disregarded the enrollment problem and the "consequent high risk nature that the Phase III trial would not produce positive results." Specifically, Plaintiffs point to a June 15, 1999 Reuters article in which a company spokesperson stated that "because the disease is relatively rare, doctors who referred patients had little experience with the disease and therefore put 31 patients who, it was later determined, did not meet the criterion for inclusion in the study."

Further, in a conference call to stock market analysts on June 16, 1999, Defendant Towarnicki stated that the medical records needed to identify persons who would fall within the patient target population, those forming ten to forty polyps per year, were not obtained and analyzed until after the Phase III trial was concluded. [FN2] Plaintiffs assert that this evidences a strong inference that CPI entered into the Phase III study knowing that they "had failed to obtain the basic medical records necessary for identifying the target population," and that to "repeatedly publish very bullish statements trumpeting the exciting stage of development of exisulind and the pivotal nature of the Phase III trial, was at least reckless and materially misleading."

FN2. CPI erroneously argues that this allegation should not be considered because it is not contained in the Complaint. (Def.'s reply Br. at 7). The allegation can be found in paragraph 62 of the Complaint.

II. STANDARD

A motion to dismiss, pursuant to Fed.R.Civ.P. 12(b)(6), tests the legal sufficiency of the complaint. *Conley v. Gibson,* 355 U.S. 41, 45-46 (1957). A court must determine whether the party making the claim would be entitled to relief under any set of facts that could be established in support of his or her claim. *Hishon v. King & Spalding,* 467 U.S. 69, 73 (1984)(citing *Conley,* 355 U.S. at 45-46); *see also Wisniewski v. Johns-Manville Corp.,* 759 F.2d 271, 273 (3d Cir.1985). In considering a Motion to Dismiss, all allegations in the complaint must be accepted as true and viewed in the light most favorable to the non-moving party. *Rocks v. City of Phila.,* 868 F.2d 644, 645 (3d Cir.1989) (citations omitted). However, the reviewing court must

consider and accept as true only those facts alleged in the complaint." *In re Aetna Inc., Sec. Litig.,* 34 F.Supp.2d 935, 941 (E.D.Pa.1999) (citations omitted). Moreover, importantly, we are mindful that at this stage in the proceedings, the court should not look to whether plaintiffs will "ultimately prevail"; it should only consider whether they should be allowed to offer evidence in support of their claims. *In re Ikon Office Solutions, Inc., Sec. Litig.,* 66 F.Supp.2d 622, 626 (E .D.Pa.1999) (quoting *In re Burlington Coat Factory Sec. Litig.,* 114 F.3d 1410, 1420 (3d Cir.1997)).

III. DISCUSSION

***5** In order to establish a claim under Section 10(b) of the Securities Exchange Act and Rule 10b 5 promulgated thereunder, [FN3] a plaintiff must prove that the defendant: (1) made misstatements or omissions of (2) a material (3) fact; (4) that the defendant acted with knowledge or recklessness and (5) that the plaintiff reasonably relied on the misrepresentation or omission and (6) consequently suffered damage. *In re Advanta Corp. Sec. Litig.,* 180 F.3d 525, 537 (3d Cir.1999)(citing *In re Westinghouse Sec. Litig.,* 90 F.3d 696, 710 (3d Cir.1996)).

FN3. Section 10(b) of the Securities exchange Act prohibits using "in connection with the purchase or sale of any security ... any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors." 15 U.S.C. § 78j(b).
Rule 10b-5 makes it unlawful for any person to:
(b) ... make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading....
17 C.F.R. § 240.10b-5.

Section 78u-4(b) of the Private Securities Litigation Reform Act (the "Reform Act") requires a plaintiff alleging a Rule 10 b 5 violation to specify each misleading statement, the reasons why each statement was misleading, and, when the allegations are based upon information and belief, all facts on which the belief is formed. [FN4] *In re Equimed, Inc. Sec. Litig.,* No. 98-CV-5374, 2000 WL 562909, at *3 (E.D.Pa. May 9, 2000) (citing 15 U.S.C. § 78u-4(b)(1)). This standard can be satisfied by identifying with particularity the sources of the facts upon which the plaintiffs' beliefs are based. *In re Aetna,* 34 F.Supp.2d at 942, 943 (citing *In re Silicon Graphics, Inc. Sec. Litig.,* 970 F.Supp. 746 (N.D.Cal.1997)).

FN4. The Reform Act states: (1) Misleading statements and omissions
In any private action arising under this chapter in which the plaintiff alleges that the defendant -
(A) made an untrue statement of material fact; or
(B) omitted to state a material fact necessary in order to make the statements made, in the light of the circumstances in which they were made, not misleading; the complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed.
(2) Required state of mind:
In any private action arising under this chapter in which the plaintiff may recover money damages only on proof that the defendant acted with a particular state of mind, the complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.
15 U.S.C. § 78u-4(b).

The Reform Act also requires plaintiffs, for each alleged act or omission, to allege "with particularity" facts that give rise to a strong inference that the defendant acted with the required state of mind. *In re Equimed,* 2999 WL 562909, at *2 (citing 15 U.S.C. § 78u-4(b)(2)). In order to establish the scienter requirement, a plaintiff must allege "facts establishing a motive and an opportunity to commit fraud," or to set forth "facts that constitute circumstantial evidence of either reckless or conscious behavior." *Id.* (quoting *In re Advanta,* 180 F.3d at 534). The facts must be stated with particularity and give rise to a "strong inference" of the required scienter. *Id.* [FN5]

FN5. However, while the Reform Act does require that these facts be pled with particularity, this language simply reflects the existing requirements for pleading fraud under Federal Rule of Civil Procedure 9. *In re Ikon Office Solutions, Inc. Sec. Litig.,* 66 F.Supp.2d 622, 627 (E.D.Pa.1999)(citing *In re Advanta Corp. Sec. Litig.,* 180 F.3d 525, 534 (3d Cir.1999)).

Finally, complaints alleging securities fraud must also comply with the heightened pleading requirement of Federal Rule of Civil Procedure 9(b), which provides that in all averments of fraud, the circumstances constituting fraud shall be stated with particularity. *In re Advanta,* 180 F.3d at 534 (citations omitted). To satisfy this burden, the plaintiff must plead "the who, what, when, where and how; the first paragraph of any newspaper story." *Id.* (citations omitted). In other words, the plaintiff must "specify the statements contended to be fraudulent, identify the speaker, state when and where the statements were made, and explain why the statements were fraudulent." *Tock v. Input/Output, Inc.* (quoting *Williams v. WMX Techs., Inc.,* 112 F.3d 175, 177 (5th Cir.), *cert. denied,* 118 S.Ct. 412 (1997)). "Plaintiffs need not, however, plead the 'date, place or time' of the fraud, so long as they use an 'alternative means of injecting precision and some measure of substantiation into their allegations of fraud.' " *In re Cendant Corp. Litig.,* 60 F.Supp.2d 354, 368 (D.N.J.1999) (citing *Rolo v. City Investing Co. Liquidating Trust,* 155 F.3d 644, 658 (3d Cir.1998); *Seville Indus. Mach. v. Southmost Mach.,* 742 F.2d 786, 791 (3d Cir.1984)). Moreover, "the Third Circuit has cautioned that courts should 'apply the rule with some flexibility and should not require plaintiffs to plead issues that may have been concealed by the defendants.' " *Id.,* (citing *Rolo,* 155 F.3d at 658; *Christidis v. First Pennsylvania Mortg. Trust,* 717 F.2d 96, 99 (3d Cir.1983)).

***6** In the instant case, CPI alleges that this Court erred in refusing to dismiss Plaintiffs' Complaint essentially because: (1) the Complaint does not allege that any of the challenged statements is false or misleading; (2) CPI's statements are protected by the safe harbor of the Reform Act or the "bespeaks caution" doctrine; and (3)the Complaint fails to adequately plead that CPI acted with the requisite scienter.

A. The scienter requirement of 15 U.S.C. § 78u-4(b)(2).

CPI argues that Plaintiffs have failed to establish the requisite scienter under the Reform Act. In order to establish scienter, a plaintiff may either show that the defendant had a motive and opportunity to commit fraud, or provide facts which constitute circumstantial evidence of either reckless or conscious behavior. *In re Advanta,* 180 F.3d at 534. The facts must be pled with particularity and give rise to a "strong inference" of scienter. *Id.*

In the instant case, this Court agrees with CPI's assertion that the Complaint does not establish motive and opportunity. [FN6] However, taking all allegations in Plaintiffs' Complaint as true, as we must at this stage, and mindful that the likelihood that Plaintiff will prevail is not proper consideration at this stage in the proceedings, we find that Plaintiffs have in fact established that CPI acted recklessly in this case. Recklessness remains a sufficient basis for liability under the Reform Act as it is "not only consistent with the Reform Act's expressly procedural language, but also promotes the policy objectives of discouraging deliberate ignorance and preventing defendants from escaping liability solely because of the difficulty of proving conscious intent to commit fraud." *In re Advanta,* 180 F.3d at 535 (citing *In re Burlington Coat Factory* 114 F.3d at 1418). A reckless statement is "one involving not merely simple, inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *Id.* (citations omitted). Scienter may be alleged by "stating with particularity facts giving rise to a strong inference of conscious wrongdoing, such as intentional fraud or other deliberate illegal behavior." *Id.* "Factual allegations of the allegedly fraudulent acts may establish recklessness." *In re Ikon,* 66 F.Supp.2d at 629 (citing *Ades v. Deloitte & Touche,* 799 F.Supp. 1493, 1500 (S.D.N.Y.1992)).

FN6. Plaintiffs have not alleged that any of the Defendants sold CPI stock at a profit. Moreover, such an allegation, even by itself, would not be enough to establish motive. *See In re Equimed,* 2000 WL 562909, at *5 (holding that no showing of motive established where no defendant was alleged to have sold stock to profit from misrepresentations and noting that such an allegation, even if made, would be

insufficient to infer fraudulent intent under *In re Advanta*).

In support of their claim that CPI acted recklessly, Plaintiffs assert that CPI failed to adequately identify members of the target population for the Phase III trial, rendering the trial incomplete and its data insufficient. (Pl.'s Br. at 31.) Plaintiffs have alleged that CPI stated that they accepted referrals from physicians with little experience with ADT and who were therefore incapable of identifying the appropriate members of the target population. *Id.* Plaintiffs further claim that CPI asserted that they did not obtain the medical records necessary to provide crucial information for identifying patients who would fall within the target group until after the Phase III trial initially failed. *Id* . Moreover, Plaintiffs assert that CPI stated that APC is such a rare disease that it was extremely difficult to formulate a program for identifying the target population that had any reliability. *Id.* Plaintiffs assert that all of CPI's top management were aware of these issues when the Phase III study was planned and implemented. *Id.* Plaintiffs point out that the fact that the study involved so few patients should have alerted CPI to the need to "force maximum effort to verify that the patients enrolled actually belonged in the study; indeed, the relatively small number should have made the review burden easier." *Id.*

***7** Based upon the above, Plaintiffs contend that without any basis for confidence in the study, CPI could not truthfully claim that enrollment for the Phase III trial had been completed, that the Phase III trial was on schedule, or that it could produce data that could lead to an NDA filing or FDA approval. *Id.* However, Plaintiffs allege that CPI did indeed make statements that the Phase III trial was proceeding as planned and that they expected to file an NDA in the first half on 1999, without revealing that the trial was flawed due to a reckless failure to select appropriate patients. *Id.* Plaintiffs further assert that in their haste to begin marketing a product after years of delay, CPI recklessly failed to comply with the most basic principles of clinical testing in the hope that satisfactory results would be obtained anyway. *Id.* at 31-32. Plaintiffs have asserted the speakers of the statements, when and to whom they were made, and that the speakers had knowledge of the potential flaws in the enrollment process. Plaintiffs also identify the sources from which they discovered the statements. We find that the above allegations sufficiently plead, with particularity, a strong inference of recklessness.

With respect to the individual Defendants, CPI challenges Plaintiffs' assertions of scienter as "boilerplate" allegations. A pleading of scienter may not be based merely upon a bare inference that a defendant "must have had" knowledge of the facts. *In re Advanta,* 180 F.3d at 539 (citations omitted). Such an inference includes allegations that a securities fraud defendant must have known a statement was false or misleading simply by virtue of his position within the company. *Id.; In re Equimed,* 2000 WL 562909, at *5. Generalized imputations will not suffice, regardless of the defendant's position within the company. *In re Advanta,* 180 F.3d at 539.

However, where the alleged fraud relates to the core business of the company, knowledge of the fraud may be imputed to the individual defendants. *In re Aetna,* 34 F.Supp.2d at 953 (distinguishing *In re Advanta* and holding that because individual defendants were in high management positions during period in which fraud was alleged to have occurred, there existed "strong circumstantial evidence" that the defendants had knowledge of undisclosed facts concerning the fraud).

Moreover, in the instant case, while Plaintiffs do make reference to the Defendants' positions within the company, the scienter allegations do not rest on their mere status within the company. Rather, Plaintiffs' allegations of the individual Defendants' knowledge is substantially more extensive. For example, Plaintiffs claim that in their respective capacities as Chief Executive Officer and Chief Scientific Officer, Defendants Towarnicki and Pamucku had "access to the adverse undisclosed information about CPI's business, operations, operational trends, finances, markets and present and future business prospects via access to internal corporate documents (including the Company's operating plans, budgets and forecasts and reports of actual operations compared thereto), conversations and connections with other corporate officers and employees, attendance at management and Board of Directors meetings and committees thereof and via reports and other information provided to them in connection therewith." (Compl.at ¶ 13(b)). Plaintiffs also state that the Defendants "directly participated in the management of the Company, [were] involved in the day-to-day operations of the Company at the highest levels and [were] privy to confidential proprietary information concerning the Company and its business, operations, growth, finances, and financial condition, as alleged herein." *Id.* at 14. Plaintiffs' Complaint also alleges that the Defendants

were "involved in the drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein, were aware (or recklessly disregarded) that the false and misleading statements were being used regarding the Company and approved or ratified these statements." *Id.* Plaintiffs also allege that the Defendants "participated in drafting, preparation, and/or approval of the various public and shareholder and investor reports and other communications complained of herein and were aware or recklessly disregarded the misstatements contained therein and omissions therefrom, and were aware of their materially false and misleading nature." *Id.* at 16. Plaintiffs also claim that the defendants had access to adverse undisclosed information which rendered the positive representations made by or about CPI and its business issued by the company materially false and misleading. *Id.* Plaintiffs claim that the defendants controlled the contents of the Security Exchange Commission filings, press releases and other public statements issued by CPI during the class period. *Id.* at 17. Plaintiffs claim that each Defendant was provided with copies of the documents alleged in the Complaint prior to or shortly after their issuance and/or had the ability and/or opportunity to prevent their issuance or cause them to be corrected." *Id.* Plaintiffs also state that defendants were involved in creating, reviewing, and approving the protocol establishing how the Phase III trials would be constructed, the criteria for selecting the persons to be enrolled and the physicians selected to refer patients, and that as a result the study did not require that physicians have adequate expertise regarding APC. *Id.* at 67. Moreover, importantly, Defendant Towarnicki is charged with having knowledge of the flaws in the Phase III trial, as evidenced by his comments in November of 1998 and in the February 2, 1999 interview with the *Bloomberg Forum. Id.* at 59. As such, Plaintiffs have done more than merely state that the Defendants must have had knowledge of the misrepresentations simply because they were high level officers. We find that these additional allegations are sufficient to overcome the prohibition against allegations of knowledge of defendants simply because of their positions in the company.

***8** Finally, CPI argues that Plaintiffs cannot establish that CPI acted with deliberate recklessness, since Plaintiffs cannot show that CPI's belief regarding the likely success of the trial was unreasonable. (Def.'s Br. at 33). CPI argues that "[a]s long as Defendants did in fact have an honest belief, 'they are not liable.' " *Id.* (quoting *McLean v. Alexander,* 599 F.2d 1190, 1198 (3d Cir.1979)). CPI relies on the *In re Advanta* court's conclusion that claims which at best allege mismanagement, as opposed to willful ignorance, are not cognizable under the federal securities laws. *In re Advanta,* 180 F.3d at 537. However, taking all allegations in the Complaint as true, we find that Plaintiffs have adequately alleged that CPI acted with deliberate recklessness in pushing forward with a clinical trial which they knew was flawed. According to Plaintiffs' allegations, if CPI was aware of the insufficiency of the trial, they could not have had an "honest belief" that the trial would likely be successful. At this stage in the proceedings, once again, it would have been inappropriate for this Court to dismiss the Complaint based merely on CPI's vehement insistence on their version of contested issues in this case.

Moreover, the *In re Aetna* court was recently faced with the question of whether securities fraud plaintiffs' claims were inactionable as due to mismanagement. *In re Aetna,* 34 F.Supp.2d at 950. That case arose out of alleged flaws in the integration of operations of the defendant and another company in connection with a corporate merger. *Id.* at 940. The court held that " a complaint is not subject to dismissal if plaintiffs plead 'specific facts permitting the inference that defendants were intentionally concealing [mismanagement].' " *Id.* (quoting *In re Westinghouse,* 90 F.3d at 711.)) The court further held that if the Complaint alleges that "a defendant was aware that mismanagement had occurred and made a material public statement of corporate affairs inconsistent with the existence of the mismanagement," the complaint states actionable mismanagement. *In re Aetna,* 34 F.Supp.2d at 950 (citing *Hayes v. Gross,* 982 F.2d 104, 106 (3d Cir.1992)). Accordingly, the court held that the plaintiffs adequately pled that the defendants made misrepresentations and omissions regarding the success of the integration process. *Id.* at 950. The court noted that while the flaws in the integration process may be due to mismanagement, the crux of the plaintiffs' claim was that the defendants made material misrepresentations and failed todisclose the facts relating to the flaws in the process. *Id.* Accordingly, the court rejected the defendants' argument that the plaintiff's allegations were merely examples of mismanagement. *Id.*

Similarly, in the instant case, Plaintiffs' have sufficiently pled that CPI made material misrepresentations with respect to the Phase III trial, and as such the claims are actionable regardless of whether the flaws in the Phase III trial were due to mismanagement. *See also In re Craftmatic Sec.*

Litig., 890 F.2d 628, 639 (3d Cir.1989) ("Although allegations of failure to disclose mismanagement alone do not state a claim under the federal securities law, a claim that the defendants failed to disclose material facts may be actionable.")

B. Misleading statements under 15 U.S.C. § 74u-4(b)(1).

***9** CPI argues that Plaintiffs have failed to plead that any of the challenged statements is false or misleading. [FN7] In support of this contention, CPI argues that the following three challenged statements are not actionable because the complaint fails to adequately plead their falsity: (1) that "exisulind can selectively induce apoptosis in precancerous cells without affecting normal cells"; (2) that CPI "was moving aggressively forward with clinical development of ... exisulind" and (3) that development efforts were "proceeding as planned," were not "materially different from those previously reported" and as such, were not known to have "accounted for recent trading patterns." [FN8] CPI argues that Plaintiffs have failed to "plead any facts, much less the particularized facts required by the Reform Act, demonstrating that any of the statements was false when made." (Def.'s Br. at 13 .) Moreover, CPI argues that although the Complaint is pled on information and belief, Plaintiffs fail to set forth factual bases for their beliefs. [FN9]

FN7. CPI first argues that approximately five of the challenged statements are not actionable as they are either unrelated to exisulind or are statements of historic fact. CPI incorrectly states that because Plaintiffs did not respond to this argument, Plaintiffs have conceded that no liability may be premised on these statements and that this Court should not consider them. (Def.'s Reply Br. at 5, n. 3). Plaintiffs' argument with regard to this issue can be found on pages 28-29 of their Brief.
CPI argues, citing *In re Advanta,* that "report[s of] previous successes" "do not create liability under section 10(b)." *In re Advanta Sec. Litig.,* 180 F.3d 525, 538 (3d Cir.1999). However, as will be discussed more fully later, although some of the statements may contain reports of facts which ultimately came true, the statements are being challenged for having been made despite CPI's knowledge of the flaws in the Phase III trial. As such, they do not escape liability as merely statements of historic fact. Further, some statements, while literally true, can become misleading to investors, due to their context and manner of their presentation. *McMahon v. Wherehouse Entertainment, Inc.,* 900 F.2d 576, 579 (2d Cir.1990). Therefore, the disclosure required by the securities laws is not measured by literal truth, but instead by the ability of the material to accurately inform rather than mislead prospective buyers. *Id.* The issue is therefore whether the statements taken as a whole and in context would have misled a reasonable investor. *Id.*

FN8. CPI claims that the rest of the statements are also protected from liability either under the safe harbor doctrine or under the bespeaks caution doctrine, which will be discussed later.

FN9. In the instant case, Plaintiffs' allegations regarding CPI's alleged misleading statements are actually based upon investigation of counsel, rather than information and belief. While the Reform Act makes clear that allegations based upon information and belief must be supported by "all facts upon which that belief is formed," it does not specify whether this "heightened pleading standard" applies to allegations which are based upon investigation of counsel. Moreover, contrary to CPI's bald assertion that there is "overwhelming authority" standing for the proposition that allegations based upon investigation of counsel are equivalent to allegations based upon information and belief and therefore require heightened pleading, (Def.'s Mem. Further Supp. Mot. Recons. or in Alternative Application Order Certifying Immediate Appeal at p. 3), the Third Circuit has not yet ruled on this issue. Furthermore, courts within this district and without are split as to this question. *See In re Equimed, Inc. Sec. Litig.,* No. 98-CV-5374, 2000 WL 562909, at *4 (E.D.Pa. May 9, 2000)(recognizing jurisdictional split and stating that "there is no binding authority on whether plaintiffs must state with particularity all facts on which their belief is formed when the allegations are based on 'investigation of counsel,' " but holding that the heightened

standard applies to such allegations). However, the determination of the appropriate standard for allegations based on investigation of counsel is not necessary to this Court's denial of the Complaint, as we find that Plaintiffs have satisfied the standard imposed upon allegations based upon information and belief. Moreover, in the event that the Third Circuit decides that allegations based upon investigation of counsel are not subject to the heightened pleading standard under the Reform Act, then based upon our reasoning as described above, Plaintiffs allegations are clearly sufficient.

At the outset, we note that CPI inaccurately, although not surprisingly, begins this line of argument with the premise that "Plaintiffs do not assert that the Phase III trial was not a success" and that "the absence of this key allegation in and of itself is telling." (Def.'s Br. at 14, 17.) CPI relies heavily upon this alleged concession for its argument that none of its statements could have been false and misleading, or that they were based upon honest belief. [FN10] However, as discussed above, Plaintiffs do indeed repeatedly insist in their brief that the trial was unsuccessful since only 34 of 65 patients fell within the target group. Moreover, Plaintiffs repeatedly question the success of the Phase III trial in light of their information that CPI has been required by the FDA to supplement its findings as a result of that trial. (Compl. at ¶ 60; Pl.'s Br. at 2, 13, 29 at n. 10). CPI has not responded to these points, and as such, the question of the success of the Phase III trial has yet to be answered and may not be relied upon by CPI as dispositive of any issue in this case. [FN11]

FN10. Indeed, CPI's Brief in support of its Motion to Dismiss assumes that the success of the Phase III trial is undeniable from the very outset. The first paragraph of the brief states "[t]he theory of this case is that Defendants should be held liable under the federal securities laws for being lucky. CPI conducted a successful clinical trial for its new drug, exisulind." (Def.'s Br. at 1.) However, CPI has provided no evidence to support its conclusion that the trial was successful, other than its own repeated insistence that it was.

FN11. As such, we find the sections in CPI's brief entitled "Defendants' Forward Looking Statements Are Immune From Liability Because They Turned Out To Be True" and "The Trial's Success Negates Any Inference That Defendants Knew It Would Fail" to be inapposite, at least at this time, and will devote no further discussion to those sections.

CPI further argues that Plaintiffs' assertions that the Phase III trial was flawed, that CPI lacked the organizational safeguards to ensure proper collection and review of the data obtained from the trial and that the physicians enrolling patients in the study were unqualified to do so all fall short of the kind of particularized pleading of the "who, what, when, where, and how" particularized pleading required by the Reform Act and Rule 9 under *In re Advanta* . CPI alleges that Plaintiffs fail to identify the flaws in the trial, who knew of them or "how they rendered statements about the status of CPI's NDA filing false or misleading when made." (Def's Br. at 14).

However, we find that Plaintiffs did adequately address these questions. Plaintiffs have alleged the nature of the statements at issue; they assert that CPI made various positive statements regarding the progress of the Phase III trial. Plaintiffs have provided the sources for their beliefs that the trial was flawed--they refer to a statement made by a company spokesperson following the trial in which the spokesperson indicated that "the unqualified patients could have been identified prior to their inclusion in the study, but that the physicians referring them, having 'little experience' with APC, failed to do so, and thus the physicians should be blamed for the study's faulty design and construction." (Compl. at ¶ 61.) Plaintiffs further refer to a statement made by Defendant Towarnicki in an interview in which he referred to design flaws in the trial which could have accounted for the apparent lack of statistical significance of the results of the Phase III trial. *Id.* at ¶ 59. Plaintiffs also allege that Defendant Towarnicki indicated that the failure to apply a sufficient "degree of scrutiny" to the Phase III patients' medical records resulted in the inclusion of ineligible patients which Plaintiffs allege "crippled" the trial. *Id.* at ¶ 62. Further, Plaintiffs have alleged why the positive statements made regarding the trial were misleading-given the Defendants' knowledge of the alleged flawed nature of the trial, the positive statements, made contemporaneously with that

knowledge, were false and/or misleading. As CPI admits, even the heightened pleading standard for allegations upon information and belief "can be satisfied by identifying the sources upon which such beliefs are based." *In re Aetna,* 34 F.Supp.2d at 942. As such, Plaintiffs have provided sufficient information regarding what statements are alleged to be false, who made them and where, and why they were false.

***10** However, relying on *In re Silicon Graphics, Inc. Sec. Litig.,* 970 F.Supp. 746 (N.D.Cal.1997), CPI seeks to require Plaintiffs, because the pleadings are upon information and belief, to provide "the names of confidential informants, employees, competitors, Government employees, members of the media, and others who have provided information leading to the filing of the case." *In re Silicon Graphics,* 970 F.Supp. at 763-764. However, regardless of the fact that *In re Silicon Graphics* is not binding on this court, we note that many of the sources of information mentioned by the court in *In re Silicon Graphics* are inapplicable to this case, e.g., confidential informants and government employees. Moreover, Plaintiffs in this case have identified the applicable sources under *In re Silicon Graphics*--they have identified the media members to whom statements were made by CPI employees as well as the dates of the press releases.

Nonetheless, CPI disregards the bases provided for Plaintiffs' beliefs, repeatedly insisting that Plaintiffs have provided no bases at all for their beliefs. (Def.'s Br. at 17.) CPI also insists that even if Plaintiffs provided some bases for their beliefs, the Reform Act's requirement of "all facts" has not been met in this case. Apparently, CPI reads *In re Advanta* as requiring that a plaintiff plead "all conceivable facts" which would support their beliefs, without the benefit of discovery. However, we do not believe that *In re Advanta* imposes quite so strict a requirement. Indeed, it is difficult to imagine how any complaint could survive so narrow a reading of that holding. Rather, the *In re Advanta* court cautioned that under the Reform Act a plaintiff must plead all facts upon which his or her belief is based. We find that Plaintiffs have done so, and that the complaint is sufficient to meet the standards imposed by *In re Advanta. See Equimed,* 2000 WL 562909, at *3 (holding Reform Act satisfied where complaint described how the defendant's earnings were misstated in "numerous filings and other statements issued by the company"); *In re Cendant Corp.,* 60 F.Supp.2d at 371-374 (holding that allegations that accounting firm failed to verify management statements, failed to investigate internal controls and acquiesced to incorrect revenue recognition alleged sufficient recklessness to survive motion to dismiss).

C. Applicability of the Bespeaks Caution Doctrine and the Reform Act's Safe Harbor.

With regard to the remaining challenged statements, CPI claims that they are shielded from liability under the bespeaks caution doctrine due to CPI's "exhaustive risk disclosures." (Def.'s Br. at 22.) The bespeaks caution doctrine "serves to neutralize forward-looking statements concerning forecasts and projections." *In re Aetna,* 34 F.Supp.2d at 946.

> When an offering document's forecasts, opinions or projections are accompanied by meaningful cautionary statements, the forward-looking statements will not form the basis for a securities fraud claim.... In other words, cautionary language, if sufficient, renders the alleged omissions or misrepresentations immaterial as a matter of law.

***11** *Id.* (quoting *In re Westinghouse,* 90 F.3d at 707; *In re Donald Trump Casino Sec. Litig.,* 7 F.3d 357, 371-72 (3d Cir.1993)).

However, the bespeaks caution doctrine is only available for forward-looking statements, and cannot be invoked for misleading statements of existing fact. *In re Aetna,* 34 F.Supp.2d at 946; *In re Mobilemedia Sec. Litig.,* 28 F.Supp.2d 901, 928 (D.N.J.1998); *In re Donald Trump,* 7 F.3d at 371; *Shaw v. Digital Equip. Corp.,* 82 F.3d 1194, 1213 (1st Cir.1996); *Voit v. Wonderware Corp.,* 977 F.Supp. 363, 371-72 (E.D.Pa.1997) [FN12]; *J/H Real Estate, Inc. v. Abramson,* 901 F.Supp. 952, 956 (E.D.Pa.1995)). As Plaintiffs have alleged that CPI made material omissions of existing facts, i.e., flaws in the Phase III trial for exisulind, and that these omissions were misleading at the time they were made, the bespeaks caution doctrine is inapplicable. [FN13]

> FN12. The decision in *In re Voit v. Wonderware Corp.,* 977 F.Supp. 363 (E.D.Pa.1997) was abrogated in part by *In re Advanta,* with respect to only the requirements for pleading scienter. The *In re Advanta* court did not address the bespeaks caution doctrine.
>
> Moreover, CPI incorrectly argues that *Voit* is inapposite because the court in that case "merely held that the bespeaks caution and safe harbor were inapplicable because plaintiff did not challenge any forward-looking misstatements or omissions." (Def.'s

Br. at 23). However, the reason that the *Voit* court found that the challenged statements were not forward- looking was because they related to omissions of present facts. *Voit,* 977 F.Supp. at 371-72.

FN13. Relying on a case outside this jurisdiction, CPI's primary argument against the application of *In re Mobilemedia* holding is that the court's holding was simply wrong, and was in violation of Congress' intent in passing the Reform Act. We disagree. While CPI essentially asserts that the safe harbor doctrine was enacted due to the difficulty companies face in predicting future risks, Plaintiffs' theory is not related to disclosure of future risks, but rather the material omissions of existing facts which rendered CPI's statements misleading. We do not agree that the Reform Act was intended to permit companies to completely avoid liability for omissions of existing material facts simply by manipulating verb tense.

Moreover, to the extent that the challenged statements were accompanied by cautionary language, such warnings, taking Plaintiffs' allegations as true, were insufficient in light of CPI's knowledge at the time the statements were made that the risks had already materialized. "Warnings of possible adverse events are insufficient to make omissions of present knowledge of certain future events legally immaterial." *In re Mobilemedia,* 28 F.Supp .2d at 930 (holding that warnings of a mere contingency when the contingency had already occurred were insufficient to warrant the application of either the safe harbor or the bespeaks caution doctrine); *In re Westinghouse* [FN14], 90 F.3d at 709 ("[D]efendants' cautionary statements about the future did not render those misrepresentations of [known losses and known risks] immaterial"); *Rubinstein v. Collins,* 20 F.3d 160, 171 (5th Cir.1994)("to caution that it is only possible for the unfavorable events to happen when they have already occurred is deceit").

FN14. CPI argues that *In re Westinghouse* is inapplicable to the instant case because it pre-dated the Reform Act. However, *In re Advanta,* the leading post-Reform Act Third Circuit case, did not address the issue of whether the failure to disclose material existing facts renders a statement misleading. As such, *In re Westinghouse* continues to represent the Third Circuit's current comment on this issue.

CPI also argues that the challenged statements are shielded from liability under the safe harbor doctrine of the Reform Act. The safe harbor provision of the Reform Act protects defendants from Rule 10 b 5 liability for certain statements which are forward-looking. *In re Advanta,* 180 F.3d at 535. A statement is shielded as forward-looking as long as the plaintiff proves it was made with "actual knowledge ... that the statement was false or misleading."

Defendants argue that each of the challenged statements regarding CPI's plans and expectations for the NDA filing for exisulind is forward-looking because the statements relate to CPI's future plans and use "language of futurity." However, "allegations based upon omissions of existing facts or circumstances do not constitute forward looking statements protected by the safe harbor of the Securities Act." *In re Mobilemedia,* 28 F.Supp.2d at 930 (holding that company's statement alleged to be misleading on the basis of omissions of facts known to company at the time the statement was made was not protected under safe harbor)(citing *In re Valujet, Inc. Sec. Litig.,* 984 F.Supp. 1472, 1479 (N.D.Ga.1997); *Voit,* 977 F.Supp. at 371) [FN15]. *See also In re Cendant Corp.,* 60 F.Supp.2d at 376 (holding that because plaintiffs alleged that defendant knew statement was false at the time it was made, statement did not fall within safe harbor).

FN15. Since we find the safe harbor to be inapplicable, we do not address its "actual knowledge" requirement.

D. Section 20(A) Claim

***12** Section 20(A) imposes joint and several liability upon any person who controls a person liable under any provision of the Exchange Act. *In re Aetna,* 34 F.Supp.2d at 957. Plaintiffs have alleged that Defendants Towarnicki and Pamucku acted as controlling persons of CPI under Section 20(A). As Plaintiffs adequately pled that the individual Defendants exercised actual control over CPI during the Class Period, we denied CPI's Motion with respect to the section 20(A) claim as well. *See In re Aetna,* 34 F.Supp.2d at 957.

BY THE COURT:

2000 WL 805221, 2000 WL 805221 (E.D.Pa.), Fed. Sec. L. Rep. P 91,001

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